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PUBLIC HEALTH SERVICE
BIOLOGICAL MATERIALS LICENSE AGREEMENT

INTERNAL USE ONLY

This **Agreement** is entered into between the National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**") through the Office of Technology Transfer, **NIH**, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A. and _____ ("**Licensee**"), a corporation of _____, having an office at _____.

1. Definitions:

   (a) "**Materials**" means the following biological materials including all progeny, subclones, and unmodified derivatives thereof: _____, as described in _____ _____ and developed in the laboratory of _____.

   (b) "**Licensed Products**" means _____.

2. **Licensee** desires to obtain a license from **PHS** to use the **Materials** provided under this **Agreement** in its commercial research or product development and marketing activities. **Licensee** represents that it has the facilities, personnel, and expertise to use the **Materials** or the **Licensed Products** for commercial purposes and agrees to expend reasonable efforts and resources to develop the **Materials** or the **Licensed Products** for commercial use or commercial research.

3. **PHS** hereby grants to **Licensee** a non-exclusive license, within its research facilities, to make, have made, use, but not to sell the **Materials** or the **Licensed Products**.

4. In consideration of the grant in Paragraph 3, **Licensee** agrees to make the following payments to **PHS**:

   (a) Within thirty (30) days of its execution of this **Agreement**, a noncreditable, nonrefundable license issue royalty of _____ dollars ($X).

   (b) A nonrefundable annual royalty of _____ dollars ($X) which shall be due and payable on January 1 of each calendar year. The annual royalty for the first calendar year of this **Agreement** is due and payable within thirty (30) days from the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1.

(c) All payments required under this **Agreement** shall be paid in U.S. dollars and payment options are listed in Appendix B. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due.

i) Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by **Licensee**; and

ii) Additional royalties may be assessed by **PHS** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **PHS** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

5. Upon receipt by **PHS** of the license issue royalty and the prorated first year annual royalty and verification of these royalties, **PHS** agrees to provide **Licensee** with samples of the **Materials**, as available, and to replace these **Materials**, as available, at reasonable cost, in the event of their unintentional destruction. **PHS** shall provide the **Materials** to **Licensee** as specified in Appendix A.

6. **Licensee** agrees to make written reports to **PHS** within sixty (60) days after the end of each calendar year. These reports shall include, but not be limited to, progress on the research and development involving the **Materials** or the **Licensed Products** and use of the **Materials** or the **Licensed Products**. **Licensee** shall submit each report to **PHS** at the Mailing Address for **Agreement** notices indicated on the Signature Page.

7. This **Agreement** shall become effective on the date when the last party to sign has executed this **Agreement**, unless the provisions of Paragraph 23 are not fulfilled, and shall expire _____ (X) years from this effective date, unless previously terminated under the terms of Paragraphs 14 or 15.

8. **Licensee** agrees to retain control over the **Materials** and the **Licensed Products**, and not to distribute them to third parties without the prior written consent of **PHS**.

9. This **Agreement** does not preclude **PHS** from distributing the **Materials** or the **Licensed Products** to third parties for research or commercial purposes.

10. By this **Agreement**, **PHS** grants no patent rights expressly or by implication to any anticipated or pending **PHS** patent applications or issued patents.

11. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE **MATERIALS** PROVIDED TO **LICENSEE** UNDER THIS **AGREEMENT**, OR THAT THE **MATERIALS** OR THE **LICENSED PRODUCTS** MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. **Licensee** accepts license rights to the **Materials** "as is", and **PHS** does not offer any guarantee of any kind.

12. **Licensee** agrees to indemnify and hold harmless the United States Government from any claims, costs, damages, or losses that may arise from or through **Licensee's** use of the **Materials** or the **Licensed Products**. **Licensee** further agrees that it shall not by its action bring the United States Government into any lawsuit involving the **Materials** or the **Licensed Products**.

13. **Licensee** agrees in its use of the **Materials** or the **Licensed Products** to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **HHS** regulations and guidelines. **Licensee** agrees not to use the **Materials** or the **Licensed Products** for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. **Licensee** agrees not to use the **Materials** or the **Licensed Products** for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.

14. **Licensee** may terminate this **Agreement** upon sixty (60) days written notice to **PHS**.

15. **PHS** may terminate this **Agreement** if **Licensee** is in default in the performance of any material obligation under this **Agreement**, and if the default has not been remedied within ninety (90) days after the date of written notice by **PHS** of the default.

16. Upon termination or expiration of this **Agreement**, **Licensee** agrees to return all **Materials** and the **Licensed Products** to **PHS**, or provide **PHS** with written certification of their destruction.

17. Within ninety (90) days of termination or expiration of this **Agreement**, **Licensee** agrees to submit a final report to **PHS**, and to submit to **PHS** payment of any royalties due.

18. **Licensee** is encouraged to publish the results of its research projects using the **Materials** or the **Licensed Products**. In all oral presentations or written publications concerning the **Materials** or the **Licensed Products**, **Licensee** shall acknowledge the contribution of Dr. _____ and the **PHS** agency supplying the **Materials**, unless requested otherwise by **PHS** or Dr. _____.

19. This **Agreement** shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this **Agreement**. **Licensee** agrees to be subject to the jurisdiction of U.S. courts.

20. This **Agreement** constitutes the entire understanding of **PHS** and **Licensee** and supersedes all prior agreements and understandings with respect to the **Materials** or the **Licensed Products**.

21. The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, the invalidity or unenforceability of any provision of this **Agreement**, shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

22. Paragraphs 11, 12, and 18 of this **Agreement** shall survive termination or expiration of this **Agreement**.

23. The terms and conditions of this **Agreement** shall, at **PHS'** sole option, be considered by **PHS** to be withdrawn from **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

PHS BIOLOGICAL MATERIALS LICENSE AGREEMENT
FOR LICENSEE'S INTERNAL USE ONLY

SIGNATURE PAGE

In Witness Whereof, the parties have executed this **Agreement** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For **PHS**:

_____ _____
Steven M. Ferguson Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Mailing Address for **Agreement** notices:

Chief, Monitoring & Enforcement Branch, DTDT
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):
by:

_____ _____
Signature of Authorized Official Date

_____
Printed Name

_____
Title

I. Official and Mailing Address for **Agreement** notices:

_____

_____

_____

II. Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

_____
Name

_____
Title

Mailing Address

_____

_____

_____

_____

Email Address: _____

Phone: _____

Fax: _____

Any false or misleading statements made, presented, or submitted to the United States Government, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

APPENDIX A – SHIPPING INFORMATION

Licensee's Shipping Contact: information or questions regarding shipping should be directed to Licensee's Shipping Contact at:

_____ _____

Shipping Contact's Name Title

Phone: () _____ Fax: () _____ E-mail: _____

Shipping Address: Name & Address to which Materials should be shipped (please be specific):

_____

Company Name & Department

Address:

_____

_____

_____

_____

APPENDIX B – ROYALTY PAYMENT OPTIONS

NIH/PHS License Agreements

****In order to process payment via Electronic Funds Transfer sender MUST supply the following information:***

Procedure for Transfer of Electronic Funds to NIH for Royalty Payments

Bank Name: Federal Reserve Bank

ABA# 021030004
TREAS NYC
BNF=/AC-75080031
OBI=Licensee Name and OTT Reference Number
Dollar Amount Wired=$$

NOTE: Only U.S. banks can wire directly to the Federal Reserve Bank. Foreign banks cannot wire directly to the Federal Reserve Bank, but must go through an intermediary U.S. bank. Foreign banks may send the wire transfer to the U.S. bank of their choice, who, in turn forwards the wire transfer to the Federal Reserve Bank.

Mailing Address for Royalty Payments:

National Institutes of Health
P.O. Box 360120
Pittsburgh, PA 15251-6120 USA

Overnight Mail for Royalty Payments only

National Institutes of Health
360120
Mellon Client Service Center
Room 670
500 Ross Street
Pittsburgh, PA 15262-0001

(412) 234-4381 (Customer Service)

Please make checks payable to: *NIH/Patent Licensing*

*The OTT Reference Number **MUST** appear on checks, reports and correspondence*